Remarks

Applicant appreciates the examination of the present application as evidenced by the final Office Action dated May 6, 2009 (hereinafter, the "Final Action"). Applicant further appreciates the indication that rejection of claims 1-24 and 34 under 35 U.S.C. § 112, second paragraph; claims 1-22, 27 and 28 under 35 U.S.C. § 102(b); claims 1-5, 7-9, 13-23, 27 and 28 under 35 U.S.C. § 102(b); and claims 1-5, 7-9, 13-22, 24-28 and 34 under 35 U.S.C. § 102(e) have been withdrawn.

Claims 1-28, 34, and 37 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,926,890 to Vogelstein et al. (hereinafter, "Vogelstein"). More specifically, in response to Applicant's arguments submitted August 27, 2008, the Examiner asserts the following:

> The Applicant argues that Vogelstein only teaches using CMV-hCGb reporter to monitor tumor growth and does not teach determining tumor metabolism.
>
> The Applicants arguments are not found persuasive because Vogelstein clearly teaches regarding using various marker proteins including hCG different promoters for expressing secretable marker expression. Vogelstein further clearly teaches monitoring therapy of transplanted tumors. Thus Vogelstein reference addresses all the claim limitations.

Final Action, page 4 (citations omitted).

Applicant respectfully disagrees. Regarding Vogelstein, Applicant provides the following point of clarification. Creatinine is a metabolite that is secreted into the urine at nearly constant rates independent of fluid balance (*See* Volgelstein, column 8 lines 56-58), and creatinine is used as an indicia to normalize changes in urinary volume output. As such, creatinine measurement has been mischaracterized as a "product of metabolism" as applied to the present technology. Applicant respectfully submits that creatinine is a "metabolite," but one that is produced irrespective of the xenograft and is unaltered by the presence of the xenograft.

The presently claimed invention, however, is directed to methods of monitoring changes in xenograft metabolism, and such changes are independent of the effects on xenograft tumor cell numbers. In contrast, Volgelstein is directed to the use of inducible reporters to detect the effects on xenograft cell growth. This distinction is affirmed in Vogelstein, for example, in the abstract stating, "a means for following growth of

experimental neoplasms" (emphasis added); column 9 lines 27-31 stating, "to assess the relationship between b-hcg levels and tumour weights" (emphasis added); column 10 line 50 stating, "to follow growth of internal tumours" (emphasis added); as well as claim 1 reciting "a method of monitoring growth of tumour cells" and "the secretable exogenous marker protein in the urine is proportional to the number of viable cells in the animal" (emphasis added). Thus, Vogelstein does not teach monitoring changes in xenograft metabolism.

Anticipation requires that each and every element of the claim be found in a single prior art reference. *W. L. Gore & Associates Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1554, 220 U.S.P.Q. 303, 313 (Fed. Cir. 1983). However, a finding of anticipation also requires that there ***must be no difference between the claimed invention and the disclosure of the cited reference as viewed by one of ordinary skill in the art.*** *See Scripps Clinic & Research Foundation v. Genentech Inc.*, 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991) (emphasis added). Additionally, the cited prior art reference ***must be enabling***, thereby placing the allegedly disclosed matter in the possession of the public. *In re Brown*, 329 F.2d 1006, 1011, 141 U.S.P.Q. 245, 249 (C.C.P.A. 1964) (emphasis added).

Applicant respectfully submits that Vogelstein does not provide all the claim recitations. Applicant also submits that Vogelstein does not provide an ***enabling*** disclosure at least where Vogelstein is clearly directed to the use of inducible reporters to detect effects on xenograft cell growth, and Vogelstein fails to teach or suggest monitoring changes in metabolism as discussed above. Moreover, such a distinction would be viewed as a difference by one of ordinary skill in the art.

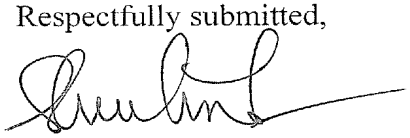
Accordingly, Applicant respectfully requests that the rejection of claims 1-28, 34, and 37 under 35 U.S.C. §102(e) be withdrawn.

CONCLUSION

Applicant respectfully submits that the present application is in condition for allowance and the same is earnestly solicited. The Examiner is encouraged to telephone the undersigned at 919-854-1400 for resolution of any outstanding issues.

Additionally, in the event that the present response does not result in receipt of a Notice of Allowance, Applicant respectfully requests the courtesy of a telephone interview to discuss the application in greater detail.

Respectfully submitted,



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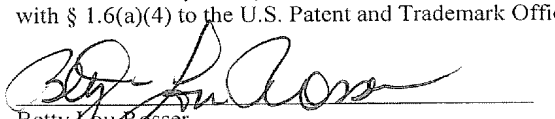

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